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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,132	09/14/2005	Stephen Strittmatter	23380-602 Natl	7561

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EXAMINER

DUTT, ADITI

ART UNIT PAPER NUMBER

1649

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/519,132

Applicant(s)

STRITTMATTER ET AL.

Examiner

Aditi Dutt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 and 7-8, drawn to a method for identifying an agent, which modulates the binding of an RGM to a Neogenin.

Group II, claim(s) 2 and 7-8, drawn to a method for monitoring the interaction between a RGM and a Neogenin, comprising the binding of the RGM protein with a Neogenin protein.

Group III, claim(s) 3-4 and 7-8, drawn to a method for monitoring the interaction between a RGM and a Neogenin, comprising the binding of a fusion protein comprising a RGM domain with cells expressing a Neogenin.

Group IV, claim(s) 5 and 7-8, drawn to a method for monitoring the interaction between a RGM and a Neogenin, by co-culturing embryonic nerve cells with cells transfected with an expression construct encoding the RGM and which express the Neogenin.

Group V, claim(s) 6-8, drawn to a method for monitoring the interaction between a RGM and a Neogenin, comprising culturing embryonic nerve cells under conditions to display growth cones. .

Group VI, claim(s) 9-11, drawn to a mixture comprising an isolated mammalian RGM and an isolated mammalian Neogenin.

Group VII, claim(s) 12, drawn to a method of enhancing axon outgrowth, by inhibiting the interaction between RGM and Neogenin.

Group VIII, claim(s) 13, drawn to a polypeptide portion of Neogenin for antagonizing the interaction between RGM and Neogenin.

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Group IX, claim(s) 14, drawn to an antibody preparation that inhibits the interaction between RGM and Neogenin.

Group X, claim(s) 15-17, drawn to a use of an inhibitor that modulates the interaction between RGM and Neogenin in the prevention or treatment of diseases associated with degeneration of vertebrate nervous tissue.

2. The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I recites the special technical feature of a identifying an agent that modulates the binding of an RGM to a Neogenin, which is not required by the other methods of Groups II-V, VII and X.

Group II recites the special technical feature of monitoring the interaction between a RGM and a Neogenin, comprising the binding of the RGM protein with a Neogenin protein, which is not required by the other methods of Groups I, III-V, VII and X.

Group III recites the special technical feature of monitoring the interaction between a RGM and a Neogenin, comprising the binding of a fusion protein comprising a RGM domain with cells expressing a Neogenin, which is not required by the other methods of Groups I, II, IV-V, VII and X.

Group IV recites the special technical feature of monitoring the interaction between a RGM and a Neogenin, by co-culturing embryonic nerve cells with cells transfected with an expression construct encoding the RGM and which express the Neogenin, which is not required by the other methods of Groups I-III, V, VII and X.

Group V recites the special technical feature of monitoring the interaction between a RGM and a Neogenin, comprising culturing embryonic nerve cells under conditions to display growth cones, which is not required by the other methods of Groups I-IV, VII and X.

Group VI recites the special technical feature of a mixture comprising an isolated mammalian RGM and an isolated mammalian Neogenin, which is not required by the other products of Groups VIII-IX.

Group VII recites the special technical feature of enhancing axon outgrowth, by inhibiting the interaction between RGM and Neogenin, which is not required by the other methods of Groups I-V and X.

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Group VIII recites the special technical feature of a polypeptide portion of Neogenin for antagonizing the interaction between RGM and Neogenin, which is not required by the other products of Groups VI and IX. Claim 13, is anticipated by prior art. Vielmetter et al., (J Cell Biol 127: 2009-2020, 1994); cited on the information disclosure statement of 23 June 2005, teaches several regions of neogenin polypeptide which are 100% identical to the amino acid sequence of SEQ ID NO: 1 of the instant application (for example, amino acids 1108-1135 of SEQ ID NO: 1 is 100% identical to amino acids 1109-1136 of neogenin peptide of the reference, see page 2012, Figure 2). Therefore, claim 13 lacks a special technical feature and cannot share one with the other claims.

Group IX recites the special technical feature of an antibody preparation, which inhibits the interaction between RGM and Neogenin, which is not required by the other products of Groups VI and VIII.

Group X recites the special technical feature of a use of an inhibitor that modulates the interaction between RGM and Neogenin in the prevention or treatment of diseases associated with degeneration of vertebrate nervous tissue, which is not required by the other methods of Group I-V and VII.

### 3. Species Election

#### A) Diseases of Vertebrate nervous tissue

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- a) Neurodegenerative diseases
- b) Nerve fiber injuries
- c) Disorders related to nerve fiber losses

The claims are deemed to correspond to the species listed above in the following manner:

Claims 16 and 17

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The following claim(s) are generic: 15.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above disorders have distinct pathology and the treatment would involve varying levels of success. For example, the special technical feature of neurodegenerative diseases is not shared by the other disorder of nerve fiber injury species.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

#### B) Neurodegenerative diseases

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The 18 species are as follows:

Motorneuronal diseases, ALS.....Riley-Day familial dysautonomia

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(Please refer to claim 17 for a complete list).

**If applicant elected the 'Neurodegenerative diseases' group as the species of Diseases of Vertebrate nervous tissue, applicant is further required to select a more specific neurodegenerative disease.**

The claims are deemed to correspond to the species listed above in the following manner: Claims 17

The following claim(s) are generic: 15 and 16

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above neurodegenerative disorders have distinct pathology and the treatment would involve varying levels of success. For example, the special technical feature of ALS is not shared by the other neurodegenerative disorders

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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**C) Nerve Fiber Injuries**

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The 9 species are as follows:

Spinal cord injuries, Brain injuries, trauma.....paraneoplastic syndromes

(Please see claim 17 for a complete list).

**If applicant elected the 'Nerve Fiber Injuries' group as the species of Diseases of Vertebrate nervous tissue, applicant is further required to select a more specific nerve fiber injury.**

The claims are deemed to correspond to the species listed above in the following manner: Claims 17

The following claim(s) are generic: 15 and 16

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above nerve fiber injuries have distinct pathology and the treatment would involve varying levels of success. For example, the special technical feature of spinal cord injury is not shared by the other nerve fiber injuries.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.



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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

D) Diseases related to nerve fiber losses

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The 6 species are as follows:

Paresis of nervus facialis.....nervus radialis

(Please see claim 17 for a complete list).

**If applicant elected the 'Disorders related to nerve fiber losses' group as the species of Diseases of Vertebrate nervous tissue, applicant is further required to select a more specific disorder related to nerve fiber loss.**

The claims are deemed to correspond to the species listed above in the following manner: Claims 17

The following claim(s) are generic: 15 and 16

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above disorders related to nerve fiber losses have distinct pathology, and the treatment would involve varying levels of success. For example, the special technical feature of paresis of nervus facialis is not shared by the other disorders of nerve fiber loss.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. In response to this Office Action/Election requirement, applicant must elect one from Groups I-X and must additionally elect a species from the diseases of vertebrate nervous tissue Group, and a species from the neurodegenerative disease, nerve fiber injury, or diseases related to nerve fiber losses group for consideration.

5. Applicant is advised that in order for the reply to this requirement to complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be

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accompanied by a petition under 37 C.F.R. 1.48(b) and by the required under 37 C.F.R. 1.17(I).

***Notice of Rejoinder***

7. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116;

amendments submitted after allowance are governed by 37 CFR 1.312.

8. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re*

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Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Advisory Information***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is 571-272-9037.

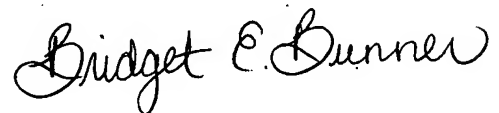
The examiner can normally be reached on M-F.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AD  
6 November 2006

A handwritten signature in cursive script that reads "Bridget E. Bunner".

**BRIDGET BUNNER  
PATENT EXAMINER**